

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

INGENUS PHARMACEUTICALS, LLC,

Plaintiff,

v.

HETERO USA, INC., HETERO LABS LTD.,
and HETERO LABS LTD. UNIT-VI,

Defendants.

C.A. No. 24-1025-JLH

PLAINTIFF'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO STAY (D.I. 49)

SMITH KATZENSTEIN & JENKINS LLP

Of Counsel:

SUGHRUE MION PLLC

Michael Dzwonczyk
John T. Callahan
L. Roman Rachuba II
2000 Pennsylvania Ave., N.W., Suite 900
Washington, D.C. 20006
Telephone: (202) 293-7060
Facsimile: (202) 293-7860
mdzwonczyk@sughrue.com
jcallahan@sughrue.com
lrachuba@sughrue.com

Neal C. Belgam (No. 2721)
Daniel A. Taylor (No. 6934)
1000 West Street, Suite 1501
Wilmington, DE 19801
(302) 652-8400
nbelgam@skjlaw.com
dtaylor@skjlaw.com

*Attorneys for Plaintiff
Ingenus Pharmaceuticals, LLC*

Dated: July 7, 2025

TABLE OF CONTENTS

TABLE OF CITATIONS	III
I. NATURE AND STAGE OF THE PROCEEDINGS	1
II. SUMMARY OF ARGUMENT	1
III. ARGUMENT	2
A. A Stay Will Simplify Issues for Trial	3
B. Discovery, Including Claim Construction, Is Not Complete	4
C. A Stay Will Not Unreasonably Prejudice Hetero	5
1. Hetero’s Conclusory Straw-Man Arguments About What Ingenus “Should Have Done” Do Not Constitute Prejudice	6
D. Collateral Estoppel Does Not Apply	6
IV. CONCLUSION	9

TABLE OF CITATIONS

Cases

<i>Astellas Pharma Inc. v. Lupin Ltd.</i> , C.A. No. 23-819-JFB-CJB, 2024 WL 1759149 (D. Del. Apr. 24, 2024)	5
<i>Biogen Int'l GmbH v. Amneal Pharm. LLC</i> , 487 F. Supp. 3d 254 (D. Del. 2020)	8
<i>Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.</i> , 402 U.S. 313 (1971)	4
<i>Deering Milliken, Inc. v. F.T.C.</i> , 647 F.2d 1124 (D.C. Cir. 1978)	6
<i>Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.</i> , 170 F.3d 1373 (Fed. Cir. 1999)	7
<i>PureWick Corp. v. Sage Products, LLC</i> , 2023 WL 2734779 (D. Del. Mar. 31, 2023)	8
<i>Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC</i> , 778 F.3d 1311 (Fed. Cir. 2015)	8

Rules

Fed. R. Civ. P. 8	6
-------------------------	---

I. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff Ingenus Pharmaceuticals, LLC (“Ingenus”) files this reply brief in support of its Motion to Stay. (D.I. 49) Since Plaintiff filed its motion, on June 25, 2025, Defendant amended its answer to incorporate a collateral estoppel defense, (D.I. 57) and has filed its answering brief in opposition to the Motion to Stay, (D.I. 60). The Court held a status conference on July 3, 2025, and has granted Defendant leave to file a motion for summary judgment on the basis of collateral estoppel in view of the final judgment in the Nexus Action.¹

II. SUMMARY OF ARGUMENT

1. There is no reason not to stay this action. The Court can resolve the merits on an appropriate schedule, if and when the matter is ripe, such as when Hetero receives tentative approval from the FDA.

2. Hetero has not articulated any prejudice associated with this proposal. It does not presently have FDA approval to launch. And it does not contend that it will be able to launch immediately upon receiving such approval. Hetero makes straw man arguments about what Ingenus should do/should have done, the failure of which ostensibly prejudices Hetero in some inarticulable way. Not only are these straw men wrong on the facts, but they are also wrong on the law and do not identify any prejudice.

3. Hetero’s conclusory citations to case law are inapposite. This includes the *Upjohn* matter that Hetero contends supports its broad assertion that it is “entitled to summary judgment” on collateral estoppel grounds. Hetero’s citations are conclusory, because they are devoid of any analysis of the underlying procedural facts associated with the entry of final judgment in the Nexus Action. For example, in the Nexus Action, Judge Rowland invalidated the ’952 Patent at summary

¹ See D.I. 50 at 1, defining “Nexus Action,” “Nexus Appeal” and “Defendant.”

judgment. There was no hearing. The court heard no evidence. Judge Rowland decided the question of invalidity on the papers. By comparison, in *Upjohn*, the district court invalidity judgment that was afforded preclusive effect by the Federal Circuit had involved a *nearly month-long jury trial*, where the jury found the patent invalid. This jury trial was followed by post-trial briefing where the court considered, and denied, plaintiff's motions for judgment as a matter of law and for a new trial. The conclusory nature of Hetero's argument is testament to the lack of commonality between these two cases.

III. ARGUMENT

Collateral estoppel does not preclude Ingenus from continuing to assert the '952 Patent in this case, because Ingenus was not afforded a full and fair opportunity to litigate the validity of the '952 Patent in the Nexus Action. In its answering brief on the Motion to Stay, and at the July 3, 2025 Status Conference, counsel for Hetero argued that its position on collateral estoppel is best represented by the *Upjohn* case. (*See*, D.I. 60 at 4-6, 9) For the many reasons discussed below in Section III.D, *Upjohn* is readily distinguishable from this case, as are the other cases cited by Hetero in its answering brief. Taken together, this case law does not support a finding of collateral estoppel in this case.

To the extent that collateral estoppel does not apply (which it does not), a stay of this action is nonetheless appropriate. A stay pending the Nexus appeal, which concerns the same '952 Patent, may resolve a number of issues for trial in this matter, including claim construction. This is especially germane at this point in the case schedule as discovery – including claim construction – is not complete. To stay the case at this point would avoid allocating resources to a claim construction that may be overturned upon resolution of the Nexus Appeal. Since discovery is not complete, no witnesses have been deposed, and expert discovery has not begun, the case schedule suits a stay. Finally, Hetero does not yet have FDA approval and is unable to launch its ANDA

Product until it has that approval. Hetero is unable to articulate any prejudice to it associated with requesting relief from the Court when it has FDA approval and is ready to launch. The Court could review briefing on collateral estoppel on an appropriate schedule at that time. For these reasons, a stay is appropriate.

A. A Stay Will Simplify Issues for Trial

Resolution of the Nexus Appeal will simplify two key questions at issue in this litigation: claim construction and indefiniteness. The *Nexus* court has already construed claim terms related to the '952 Patent, and that claim construction is subject to the Nexus Appeal, which includes “the Judgement entered on May 9, 2025 in Civil Action No. 22-cv-02868 (MMR), and all other rulings, conclusions, determinations, findings, opinions and orders that were adverse to Ingenus including the Memorandum Opinion and Order entered on May 9, 2025.” (D.I. 50, Ex. B at 1) Since the court’s ruling on claim construction falls within the scope of this language, it is also properly the subject of appeal to the Federal Circuit. Therefore, any appeal of the construction of the '952 Patent in the Nexus Action will directly impact the construction of the '952 Patent in this matter. Resolution of that claim construction may simplify claim-construction related issues for trial in this matter.

Additionally, Hetero has asserted that certain terms of the claims of the '952 Patent are indefinite. This should likely be an issue for trial that would be simplified by a ruling in the Nexus Appeal on the question of indefiniteness of these terms in the '952 Patent. In fact, this Court has previously declined to engage the defense of indefiniteness as to the '952 Patent as part of claim construction. In February 2024, in a matter involving assertion of the '952 Patent against Accord Healthcare, Inc., this Court was apprised of the then-pending claim construction in the Nexus Action – the Court denied the Parties’ motions for claim construction and ordered “[t]he Court will hear the indefinite defense(s) at the bench trial.” *Ingenus Pharmaceuticals, LLC et al v. Accord*

Healthcare, Inc., C.A. No. 23-377-JLH, D.I. 37 (February 28, 2024 Oral Order). In this case, Hetero has also raised an indefiniteness defense that should rightly be informed by the Federal Circuit’s findings on these same issues involving the ’952 Patent, including the court’s construction of terms of the ’952 Patent in the Nexus Action.

For these reasons, a stay will simplify issues for trial in this matter.

Hetero argues that a stay will not simplify issues for trial, because Ingenus allegedly “has offered no substantive argument as to why collateral estoppel does not clearly apply here[.]” (D.I. 60 at 7) This is incorrect. First, Hetero did not amend its answer and counterclaims to include the affirmative defense of collateral estoppel until *after* Ingenus moved to stay. (D.I. 57) And Hetero has not yet (at the time of filing of this reply brief) filed a dispositive motion. Therefore, it is wrong to fault Ingenus for “failing” to preemptively brief a hypothetical, yet-to-be filed motion based upon an unpleaded affirmative defense. *Blonder-Tongue Labs., Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 350 (1971) (“Res judicata and collateral estoppel are affirmative defenses that must be pleaded.”). As is discussed below in Section III.D, Hetero’s conclusory case citations (D.I. 60 at 3-6) are inapposite to the facts in the Nexus Action and do not warrant applying collateral estoppel in this matter.

B. Discovery, Including Claim Construction, Is Not Complete

The case schedule also favors a stay. As discussed above, the Parties and the Court have not invested resources in a claim construction that may be overturned by the Nexus Appeal. To the extent that Hetero seeks to argue that various claim terms of the ’952 Patent are indefinite, an issue also raised in the Nexus Action and likely the subject of the Nexus Appeal, the Court will likely defer these issues for trial. Since expert discovery has not begun and no witnesses have been deposed, the schedule favors a stay.

C. A Stay Will Not Unreasonably Prejudice Hetero

Hetero has acknowledged that, should the Federal Circuit rule in favor of Ingenus in the Nexus Appeal, Hetero will not launch its ANDA Product while this litigation is pending. Therefore, there is only one scenario in which this Court would need to address the question of collateral estoppel, and that would be if the FDA grants Hetero tentative approval to launch its ANDA Product during the pendency of the Nexus Appeal. In that case, Hetero, does not identify any prejudice to it and instead argues that asking the Court to address the question of an injunction will “burden” the Court. (D.I. 60 at 8)

Hetero also argues that the 30-month stay will expire long before this case is ready for trial (*id.*), but Hetero did not need to mirror the indefiniteness arguments of the Nexus Action in this litigation and to tie the outcome of this litigation to the arguments made in that case. Hetero opted to link the two cases and to claim the same relief now subject to the Nexus Appeal. Therefore, the resulting schedule does not prejudice Hetero.

Finally, with respect to prejudice, Hetero contends that “if Ingenus wants to preclude a potential product launch while its appeal is pending, the correct procedure is to seek such relief from the Federal Circuit pending appeal (which it has not done in the *Nexus* appeal in any event).” (D.I. 60 at 9 (citing *Astellas Pharma*)) This is nonsense. *Astellas Pharma* contains no such holding discussing the “correct procedure” for injunctive relief. *Astellas Pharma Inc. v. Lupin Ltd.*, C.A. No. 23-819-JFB-CJB, 2024 WL 1759149, at *1 (D. Del. Apr. 24, 2024). The case is also irrelevant to the question of what would happen should Hetero receive tentative approval from the FDA while this matter is stayed pending the Nexus Appeal. In that case, this Court would have jurisdiction over Hetero and any injunctive relief that Ingenus would seek related to Hetero’s potential introduction of its ANDA Product. At the same time, Hetero would not be a party to the

Nexus Appeal, and therefore the Federal Circuit would not have jurisdiction over Hetero and would not be able to grant the injunctive relief in question.

1. Hetero’s Conclusory Straw-Man Arguments About What Ingenus “Should Have Done” Do Not Constitute Prejudice

Hetero’s answering brief makes other arguments that are also wrong on the facts and on the law. In one example, Hetero essentially argues that it will be prejudiced if it has to litigate the ’952 Patent. It oddly contends that Ingenus has somehow committed a fatal procedural flaw in filing the Motion to Stay, because Ingenus allegedly “needed to move to stay entry of [] judgment [in the Nexus Action] pending appeal[.]” (D.I. 60 at 6 (citations omitted)) This is wrong. First, on May 5, 2025, Judge Rowland issued a single opinion and order in the Nexus Action explaining the court’s reasoning on summary judgment, entering final judgment and closing the case. (D.I. 50, Ex. A at 18) Second, none of the cases cited by Hetero stand for the proposition that the *only remedy* for a party facing a final judgment with the potential to create collateral estoppel is to stay that final judgment. (D.I. 60 at 6) Rather, for example “[t]he only consequence of failing to obtain a stay is that the prevailing party may treat the judgment of the district court as final[.]” *Deering Milliken, Inc. v. F.T.C.*, 647 F.2d 1124, 1129 & n.11 (D.C. Cir. 1978) (citation omitted). Ingenus has not argued that the final judgment in the Nexus Action is not a final judgment, and Hetero does not identify any place where Ingenus has made such an argument. Meanwhile, as argued herein, collateral estoppel does not apply. Third, Ingenus is fully within its rights to move to stay this action or even to move the Court to defer its ruling on collateral estoppel.

D. Collateral Estoppel Does Not Apply

As discussed earlier, when Ingenus filed the Motion to Stay, Hetero had not amended its pleadings to add the affirmative defense of collateral estoppel. *See* Fed. R. Civ. P. 8(c) (“In responding to a pleading, a party must affirmatively state any avoidance or affirmative defense,

including: . . . estoppel[.]”). Nor has Hetero yet filed a motion for summary judgment based upon collateral estoppel. And yet, Hetero faults Ingenus for not offering “any rebuttal” to the cases it has since cited in its answering brief on the Motion to Stay. (D.I. 60 at 5) Elsewhere, Hetero avers (without citation or explanation) that “[t]here is no suggestion that Ingenus lacked a fair opportunity to litigate validity before the Northern District of Illinois.” (*Id.* at 9)

The facts of the Nexus Action are simple. The *Nexus* court construed relevant claim terms. The court allowed the parties to brief summary judgment. The Defendant, Nexus, moved for summary judgment on the grounds that certain claim terms of the ’952 Patent are indefinite. The court did not hear evidence and did not hold oral argument. The *Nexus* court issued its opinion and order entering final judgment of invalidity of the ’952 Patent and closing the case in a single filing on the docket on May 9, 2025. In short, Ingenus did not have a full and fair opportunity to litigate this specific issue.

By contrast, Hetero cites a number of cases that it contends apply here.² Their lead case, *Upjohn*, is inapposite. In that case, the Federal Circuit found that the appellant was “accorded a full and fair opportunity to litigate.” *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1380 (Fed. Cir. 1999). The facts of *Upjohn* are as follows. Upjohn asserted its patent at a nearly month-long jury trial where the jury found the patent to be invalid. *Id.* Upjohn then moved for judgment as a matter of law and for a new trial. *Id.* The court then “rendered a careful, methodical analysis supporting the jury’s verdicts of invalidity and unenforceability.” *Id.* In this case, there was no jury trial followed by a verdict of invalidity. There was also no post-trial briefing on the subject of invalidity. Instead, the court entered final judgment the same day it issued its

² Ingenus addresses the cases discussed in the text of the brief, not the ones included in string cites without any explanation or analysis.

opinion, leaving no opportunity for even a motion for reconsideration, much less the motion to stay that Hetero contends should have been filed. Hetero's citation to this case is conclusory, because it repeatedly states the legal standards considered and the Federal Circuit's conclusions without any discussion of the procedural facts as they relate to this case. (D.I. 60 at 1, 4, 5, 6, 9) On the relevant facts and procedure, *Upjohn* is simply not analogous to this case.

Hetero cites *Soverain Software*, (*id.* at 3-4), which is not analogous to this case. In *Soverain*, the Federal Circuit had ruled a patent was invalid in an appeal of a first case on the same patent. *See generally, Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311 (Fed. Cir. 2015). The patent owner appealed a final judgment in a second case based upon the Federal Circuit's invalidity holding and argued that it did not have a full and fair opportunity to litigate in the first appeal, because "it would have raised different or additional arguments on [the first] appeal had it known that this court might reverse the district court on invalidity rather than only granting a new trial." *Id.* at 1317. The *Soverain* court held that the patent owner had a full and fair opportunity to litigate validity in the first trial and appeal. *Id.* By contrast, the Nexus Action did not proceed to trial and has not yet been through an appeal.

Similarly, the *Biogen* case also reflects a judgment of invalidity after a bench trial on the merits, followed by post-trial briefing. *Biogen Int'l GmbH v. Amneal Pharm. LLC*, 487 F. Supp. 3d 254, 264 (D. Del. 2020). Also, in *PureWick*, the court found collateral estoppel after an earlier trial on the merits in which a jury found the patent invalid, and the court upheld the verdict after post-trial briefing. *See generally, PureWick Corp. v. Sage Products, LLC*, 2023 WL 2734779 (D. Del. Mar. 31, 2023) These cases have a common theme not present in the Nexus Action – a trial on the merits followed by post-trial briefing. For these reasons, the cited cases are not analogous and do not support judgment against Ingenus on collateral estoppel grounds.

IV. CONCLUSION

For the reasons stated above, collateral estoppel does not apply, and all three factors favor a stay. Therefore, this matter should be stayed pending resolution of the Nexus Appeal.

Dated: July 7, 2025

SMITH KATZENSTEIN & JENKINS LLP

Of Counsel:

Michael Dzwonczyk
John T. Callahan
L. Roman Rachuba II
SUGHRUE MION PLLC
2000 Pennsylvania Ave., N.W., Suite 900
Washington, D.C. 20006
Telephone: (202) 293-7060
Facsimile: (202) 293-7860
mdzwonczyk@sughrue.com
jcallahan@sughrue.com
lrachuba@sughrue.com

/s/ Daniel A. Taylor

Neal C. Belgam (No. 2721)
Daniel A. Taylor (No. 6934)
1000 West Street, Suite 1501
Wilmington, DE 19801
(302) 652-8400
nbelgam@skjlaw.com
dtaylor@skjlaw.com

*Attorneys for Plaintiff Ingenus
Pharmaceuticals, LLC*